Devi, S.
09/719379

FILE 'CAPLUS, MEDLINE, BIOSIS, EMBASE, WPIDS, JICST-EPLUS, JAPIO, PHIC, PHIN, TOXCENTER, PASCAL, FEDRIP, DISSABS' ENTERED AT 09:04:06 ON 24 NOV 2004

L1	291	SEA ABB=ON	PLU=ON	"BAKALETZ L"?/AU
L2	46	SEA ABB=ON	PLU=ON	"DEQUESNE G"?/AU
L3	1	SEA ABB=ON	PLU=ON	"LOBERT Y"?/AU
L4	1	SEA ABB=ON	PLU=ON	L1 AND L2 AND L3
L5	7	SEA ABB=ON	PLU=ON	L1 AND (L2 OR L3)
L6	1	SEA ABB=ON	PLU=ON	L2 AND L3
L7	136	SEA ABB=ON	PLU=ON	(L1 OR L2 OR L3) AND (VACCIN? OR IMMUNIS? OR IMMUNIZ?)
L8	88	SEA ABB=ON	PLU=ON	L7 AND (POLYPEPTIDE OR PEPTIDE OR POLYPROTEIN OR PROTEIN)
L9	22	SEA ABB=ON	PLU=ON	L8 AND CHIMER?
L10	27	SEA ABB=ON	PLU=ON	L4 OR L5 OR L6 OR L9
L11	11	DUP REM L10	(16 DUPLICATES REMOVED)	

L11 ANSWER 1 OF 11 WPIDS COPYRIGHT 2004 THE THOMSON CORP on STN

ACCESSION NUMBER: 2003-810881 [76] WPIDS
CROSS REFERENCE: 1999-044514 [04]; 2003-615247 [58]
DOC. NO. CPI: C2003-225221
TITLE: Novel synthetic **chimeric** fimbrin **peptide** LB1 or LB2 comprising a first **peptide** unit, T cell epitope as second **peptide** unit and third linker **peptide** unit, useful for preventing or reducing severity of otitis media.
DERWENT CLASS: B04 D16
INVENTOR(S): **BAKALETZ, L O**; KAUMAYA, P T P
PATENT ASSIGNEE(S): (BAKA-I) BAKALETZ L O; (KAUM-I) KAUMAYA P T P
COUNTRY COUNT: 1
PATENT INFORMATION:

PATENT NO	KIND	DATE	WEEK	LA	PG
US 2003113344	A1	20030619	(200376)*		15

APPLICATION DETAILS:

PATENT NO	KIND	APPLICATION	DATE
US 2003113344	A1 Div ex	US 1998-148711	19980904
		US 2002-223711	20020819

FILING DETAILS:

PATENT NO	KIND	PATENT NO
US 2003113344	A1 Div ex	US 6436405

PRIORITY APPLN. INFO: US 1998-148711 19980904; US 2002-223711 20020819
AN 2003-810881 [76] WPIDS
CR 1999-044514 [04]; 2003-615247 [58]
AB US2003113344 A UPAB: 20031125
NOVELTY - A synthetic **chimeric** fimbrin **peptide** LB1 or

LB2 (I) comprises a first **peptide** unit (II) having a fully defined sequence of 18 amino acids as given in the specification, a second **peptide** unit (III) containing a T cell epitope and a third linker **peptide** (IV) which connects the (II) to (III), is new.

DETAILED DESCRIPTION - A synthetic **chimeric** fimbrin **peptide** LB1 or LB2 (I) comprising a first **peptide** unit (II) having a amino acid sequence (A1) or (A2), a second **peptide** unit (III) containing a T cell epitope and a third linker **peptide** (IV) which connects the (II) to (III).

An INDEPENDENT CLAIM is also included for a synthetic **peptide** having the amino acid sequence (A1) or (A2).

Arg-Ser-Asp-Tyr-Lys-Phe-Tyr-Glu-Asp-Leu-Asn-Gly-Thr-Arg-Asn-His-Lys-Lys (A1)

Tyr-Gln-Trp-Leu-Thr-Arg-Val-Gly-Lys-Tyr-Arg-Pro-Gln-Asp-Lys-Pro-Asn-Thr (A2)

ACTIVITY - Auditory; Antiinflammatory.

Nasopharyngeal colonization by non typable Haemophilus influenzae (NTHi) was examined. Five cohorts of four chinchillas each were actively **immunized** with one of the following preparations in complete Freund's adjuvant or saline control preparation; 100 micro g of the synthetic **chimeric** fimbrin **peptide** LB1, 100 micro g of a total outer membrane **protein** preparation from strain 1128, 100 micro g of the synthetic **chimeric** fimbrin **peptide** LB2, 10 micro g isolated fimbrin **protein** preparation from strain 1128. The total outer membrane preparation and fimbrin were assessed for endotoxin content prior to their use as an immunogen by a chromogenic Amoebocyte Lysate assay. The preparations were subcutaneously injected into the chinchillas. Then 30 days later the animals received a booster of one-half of the initial dosage of the same immunogen but in incomplete Freund's adjuvant. Ten days later they received 6 multiply 106 TCID50 adenovirus intranasally. Thereafter, these five cohorts were divided into two groups each and challenged intranasally, about 5 multiply 107 colony forming units (cfu) of NTHi strain 1128. The chinchillas were subject to nasopharyngeal lavage over a 21 day period, and the lavage fluid was examined and quantified for NTHi. The NTHi concentration was determined by plating on selective media. The NTHi lavage fluid concentration was plotted over time. **Immunization** with LB1 and LB2 lowered the NTHi in lavage fluid to 0 by day 21 in contrast to the control fluid which had 104 NTH1 present on day 21. The LB2 performed less well at the higher challenge dose of bacteria. Nasopharyngeal colonization is an initial step required for the development of the disease, otitis media. Since the **immunization** with synthetic **chimeric** fimbrin **peptide** inhibits nasopharyngeal colonization of NTHi, the synthetic **chimeric** fimbrin **peptides** inhibit the development of otitis media.

MECHANISM OF ACTION - **Vaccine**.

USE - (I) is useful for inducing an immune response in animals against non-typable Haemophilus influenzae (NTHi), which involves administering an immunogenic composition (V) comprising (I) and a carrier (claimed). (I) is useful for preventing or reducing adherence of NTHi to host cells thereby preventing or reducing the severity of otitis media. (I) is useful in laboratory assays, e.g., to detect antibodies in sera to NTHi.

DESCRIPTION OF DRAWING(S) - The figure shows a graph representing the concentration of NTHi (5 multiply 108 cfu NTHi/animal) in nasopharyngeal lavage fluid over time in animals **immunized** with LB1, LB2, outer

membrane **protein**, fimbrin, and control.
Dwg.4/5

L11 ANSWER 2 OF 11 CAPLUS COPYRIGHT 2004 ACS on STN
ACCESSION NUMBER: 2003:598794 CAPLUS
DOCUMENT NUMBER: 139:195895
TITLE: Efficacy of the 26-kilodalton outer membrane **protein** and two P5 fimbrin-derived immunogens to induce clearance of nontypeable Haemophilus influenzae from the rat middle ear and lungs as well as from the chinchilla middle ear and nasopharynx
AUTHOR(S): Kyd, Jennelle M.; Cripps, Allan W.; Novotny, Laura A.; **Bakaletz, Lauren O.**
CORPORATE SOURCE: Division of Science and Design, Gadi Research Centre, University of Canberra, Canberra, Australia
SOURCE: Infection and Immunity (2003), 71(8), 4691-4699
CODEN: INFIBR; ISSN: 0019-9567
PUBLISHER: American Society for Microbiology
DOCUMENT TYPE: Journal
LANGUAGE: English
AB The rat middle ear and lung clearance model has been used to show that the non-typeable Haemophilus influenzae 26-kDa outer membrane **protein** OMP26 is highly efficacious as a mucosal immunogen, inducing significantly enhanced clearance in **immunized** rats upon direct challenge of these two anat. sites. Similarly, the chinchilla model of middle ear and nasopharyngeal clearance has been used to show that two P5 fimbrin adhesin-derived immunogens, LB1 and lipoprotein D (LPD)-LB1(f)2,1,3, are highly efficacious as parenteral immunogens. Both induced significantly augmented clearance of non-typeable H. influenzae upon challenge of these sites. Here, these three non-typeable H. influenzae immunogens in addition to six bovine serum albumin and keyhole limpet hemocyanin conjugates of the synthetic **peptide** LB1(f) were assayed for relative efficacy in the reciprocal rodent model system. OMP26 was assayed in the chinchilla host by a parenteral **immunization** route, with clearance of the middle ear and nasopharynx used as outcome measures. Both LB1 and LPD-LB1(f)2,1,3 were assayed in the rat host with a mucosal **immunization** route and clearance of non-typeable H. influenzae from the lungs and middle ears as outcome measures. Both of the immunogens were found to induce a high-titered and specific immune responses in the heterologous host system. Moreover, each was highly efficacious in the reciprocal host system, providing strong support for the continued development and inclusion of both OMP26 and P5 fimbrin-derived **peptides** as candidate **vaccine** antigens directed at otitis media caused by non-typeable H. influenzae.
REFERENCE COUNT: 32 THERE ARE 32 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L11 ANSWER 3 OF 11 CAPLUS COPYRIGHT 2004 ACS on STN
ACCESSION NUMBER: 2002:107146 CAPLUS
DOCUMENT NUMBER: 136:166052
TITLE: **Vaccine** composition
INVENTOR(S): Berthet, Francois-Xavier Jacques; Dalemans, Wilfried; Denoel, Philippe; **Dequesne, Guy**; Feron, Christiane; Garcon, Nathalie; Lobet, Yves; Poolman, Jan; Thiry, Georges; Thonnard, Joelle; Voet, Pierre
PATENT ASSIGNEE(S): Smithkline Beecham Biologicals SA, Belg.

SOURCE: PCT Int. Appl., 125 pp.
CODEN: PIXXD2
DOCUMENT TYPE: Patent
LANGUAGE: English
FAMILY ACC. NUM. COUNT: 2
PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
WO 2002009746	A2	20020207	WO 2001-EP8857	20010731
WO 2002009746	A3	20020613		
WO 2002009746	C1	20021114		
W: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, AM, AZ, BY, KG, KZ, MD, RU, TJ, TM				
RW: GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW, AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR, BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG				
EP 1208214	A2	20020529	EP 2000-956369	20000731
R: AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LI, LU, NL, SE, MC, PT, IE, SI, LT, LV, FI, RO, MK, CY, AL				
AU 2001085856	A5	20020213	AU 2001-85856	20010731
EP 1307224	A2	20030507	EP 2001-965152	20010731
R: AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LI, LU, NL, SE, MC, PT, IE, SI, LT, LV, FI, RO, MK, CY, AL, TR				
US 2004126389	A1	20040701	US 2003-343561	20030915

PRIORITY APPLN. INFO.:

EP 2000-956369	A	20000731
GB 2001-3170	A	20010208
GB 1999-18319	A	19990803
WO 2000-EP7424	W	20000731
WO 2001-EP8857	W	20010731

AB The present invention relates to the field of **vaccine** formulation, particularly the field of novel adjuvant compns. comprising outer membrane vesicles (or blebs), and advantageous methods of detoxifying these compns., and advantageous methods of use of such adjuvants. The novel adjuvant for Gram-neg. bacterial **vaccine** is a capsular polysaccharide or detoxified lipid A portion of LPS derived from engineered Neisseria meningitidis serogroup A, B, Y or W; Hemophilus influenzae; Streptococcus pneumoniae; or Moraxella catarrhalis. These engineered bacteria have reduced or switched off expression of one or more gene selected from htrB, msbB, .pxK, pmrA, pmrB, pmrE, pmrF, galE, siaA, siaB, siaC, siaD, ctrA, ctrB, ctrC and ctrD. **Vaccines** comprising the adjuvant and pathogen-derived antigen is especially useful for protecting elderly patients against the pathogen.

L11 ANSWER 4 OF 11 WPIDS COPYRIGHT 2004 THE THOMSON CORP on STN
ACCESSION NUMBER: 2003-615247 [58] WPIDS
CROSS REFERENCE: 1999-044514 [04]; 2003-810881 [76]
DOC. NO. CPI: C2003-167727
TITLE: Synthetic **chimeric** fimbrin **peptide**, useful for treating Haemophilus influenzae infections.
DERWENT CLASS: B04

INVENTOR(S): **BAKALETZ, L O**; KAUMAYA, P T P
PATENT ASSIGNEE(S): (OHIS) UNIV OHIO STATE
COUNTRY COUNT: 1
PATENT INFORMATION:

PATENT NO	KIND	DATE	WEEK	LA	PG
US 6436405	B1	20020820	(200358)*		16

APPLICATION DETAILS:

PATENT NO	KIND	APPLICATION	DATE
US 6436405	B1 Cont of	US 1995-460502	19950602
		US 1998-148711	19980904

FILING DETAILS:

PATENT NO	KIND	PATENT NO
US 6436405	B1 Cont of	US 5843464

PRIORITY APPLN. INFO: US 1995-460502 19950602; US 1998-148711 19980904
AN 2003-615247 [58] WPIDS
CR 1999-044514 [04]; 2003-810881 [76]
AB US 6436405 B UPAB: 20031125
NOVELTY - A synthetic **chimeric** fimbrin **peptide** (I), comprising 12-18 residues of an 18 amino acid sequence (S1), given in the specification, is new.

DETAILED DESCRIPTION - INDEPENDENT CLAIMS are also included for:
(1) a synthetic **chimeric peptide** comprising (I), a **peptide** linker and a T cell epitope;
(2) a synthetic **chimeric peptide** comprising 12-18 residues of an 18 amino acid sequence (S2), given in the specification, a **peptide** linker and a T cell epitope; and
(3) an immunogenic composition which induces an immune response against non-typable Haemophilus influenzae, comprising the **peptide** of (1) and a carrier.

ACTIVITY - Antibacterial; Auditory.
Two rabbits were **immunized** with 500 micro g LB1 synthetic **chimeric** fimbrin **peptide** in complete Freund's adjuvant (CFA), and a second dose of 400 micro g 21 days later. A third dose of 400 micro g in CFA was administered 42 days later. Sera was obtained three weeks after the final dose, and enzyme linked immunosorbent assay was used to determine the titer of the rabbit sera. The titer was 20000 for LB1 in CFA, and 100000 for LB1 in phosphate buffered saline.

MECHANISM OF ACTION - None given.

USE - For treating a Haemophilus influenzae infection (claimed) and otitis media.

ADVANTAGE - The synthetic **peptides** do not require tedious purification techniques.
Dwg.0/5

L11 ANSWER 5 OF 11 CAPLUS COPYRIGHT 2004 ACS on STN DUPLICATE 1
ACCESSION NUMBER: 2002:724897 CAPLUS

DOCUMENT NUMBER: 138:88294
TITLE: Detection and characterization of pediatric serum antibody to the OMP P5-homologous adhesin of nontypeable Haemophilus influenzae during acute otitis media
AUTHOR(S): Novotny, Laura A.; Pichichero, Michael E.; Denoel, Philippe A.; Neyt, Cecil; Vanderschrick, Sylvie; **Dequesne, Guy; Bakaletz, Lauren O.**
CORPORATE SOURCE: Department of Pediatrics, Div. Mol. Med., Coll. Med. & Public Health, Children's Res. Inst., The Ohio State University, Columbus, OH, 43205-2696, USA
SOURCE: Vaccine (2002), 20(29-30), 3590-3597
CODEN: VACCDE; ISSN: 0264-410X
PUBLISHER: Elsevier Science Ltd.
DOCUMENT TYPE: Journal
LANGUAGE: English
AB The authors reported earlier that antibody in sera collected from seven children with acute otitis media (AOM) due to nontypeable Haemophilus influenzae (NTHI) recognized immunodominant regions of P5-fimbrin just as the authors had observed in a chinchilla model of exptl. NTHI-induced AOM. To expand upon those preliminary findings, the authors further characterized pediatric serum antibodies directed against this adhesin during AOM. Collectively, the data show that children respond immunol. to P5-fimbrin and they do so in a manner that allows for the distinction of sequence diversity within short linear peptides representing a focused region of this surface-exposed protein. The immune recognition the authors observed encourages the authors to further develop a P5-fimbrin based vaccine component.
REFERENCE COUNT: 36 THERE ARE 36 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L11 ANSWER 6 OF 11 CAPLUS COPYRIGHT 2004 ACS on STN DUPLICATE 2
ACCESSION NUMBER: 1999:795699 CAPLUS
DOCUMENT NUMBER: 132:49016
TITLE: **Vaccine**
INVENTOR(S): **Bakaletz, Lauren O.**; Cohen, Joseph; **Dequesne, Guy**; Lobet, Yves
PATENT ASSIGNEE(S): Smithkline Beecham Biologicals SA, Belg.; Ohio State University Research Foundation
SOURCE: PCT Int. Appl., 68 pp.
CODEN: PIXXD2
DOCUMENT TYPE: Patent
LANGUAGE: English
FAMILY ACC. NUM. COUNT: 1
PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
WO 9964067	A2	19991216	WO 1999-US11980	19990528
WO 9964067	C2	20020815		

W: AE, AL, AU, BA, BB, BG, BR, CA, CN, CZ, EE, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KP, KR, LC, LK, LR, LT, LV, MG, MK, MN, MX, NO, NZ, PL, RO, SG, SI, SK, SL, TR, TT, UA, US, UZ, VN, YU, ZA, AM, AZ, BY, KG, KZ, MD, RU, TJ, TM
RW: GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW, AT, BE, CH, CY, DE, DK,

ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG

CA 2330238	AA	19991216	CA 1999-2330238	19990528
AU 9941021	A1	19991230	AU 1999-41021	19990528
AU 761293	B2	20030529		
EP 1083926	A1	20010321	EP 1999-924543	19990528
R: AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LI, LU, NL, SE, MC, PT, IE, SI, FI				
BR 9910973	A	20010918	BR 1999-10973	19990528
JP 2002517218	T2	20020618	JP 2000-553135	19990528
NZ 508616	A	20030926	NZ 1999-508616	19990528
NO 2000006191	A	20010207	NO 2000-6191	20001206
ZA 2000007255	A	20020207	ZA 2000-7255	20001207
PRIORITY APPLN. INFO.:			GB 1998-12613 A	19980611
			WO 1999-US11980 W	19990528

AB Provided are **peptides** comprising antigenic determinant site of P5-like fimbrin **protein** of non-typeable Haemophilus influenzae for use as **vaccine** against otitis media, sinusitis, conjunctivitis and lower respiratory tract infection. Also provided are **chimeric polypeptides** comprising the above **peptide** and a carrier containing T cell epitope or lipoprotein D, as well as DNA or RNA mol. encoding them, antibodies, DNA probes and primers.

L11 ANSWER 7 OF 11 CAPLUS COPYRIGHT 2004 ACS on STN
ACCESSION NUMBER: 1999:651532 CAPLUS
DOCUMENT NUMBER: 131:335672
TITLE: Protection against development of otitis media induced by nontypeable Haemophilus influenzae by both active and passive **immunization** in a chinchilla model of virus-bacterium superinfection. [Erratum to document cited in CA131:156806]
AUTHOR(S): **Bakaletz, Lauren O.**; Kennedy, Bobbie-Jo; Novotny, Laura A.; Duquesne, Guy; Cohen, Joe; Lobet, Yves
CORPORATE SOURCE: Division of Otologic Research, Department of Otolaryngology, College of Medicine, The Ohio State University, Columbus, OH, USA
SOURCE: Infection and Immunity (1999), 67(10), 5545
CODEN: INFIBR; ISSN: 0019-9567
PUBLISHER: American Society for Microbiology
DOCUMENT TYPE: Journal
LANGUAGE: English
AB On page 2746, byline, line 2: "DUQUESNE" should read "DEQUESNE". The corrected Fig. 6 is given.

L11 ANSWER 8 OF 11 CAPLUS COPYRIGHT 2004 ACS on STN DUPLICATE 3
ACCESSION NUMBER: 1999:350379 CAPLUS
DOCUMENT NUMBER: 131:156806
TITLE: Protection against development of otitis media induced by nontypeable Haemophilus influenzae by both active and passive **immunization** in a chinchilla model of virus-bacterium superinfection
AUTHOR(S): **Bakaletz, Lauren O.**; Kennedy, Bobbie-Jo; Novotny, Laura A.; Duquesne, Guy; Cohen, Joe; Lobet, Yves

CORPORATE SOURCE: Division of Otologic Research, Department of Otolaryngology, College of Medicine, The Ohio State University, Columbus, OH, USA
SOURCE: Infection and Immunity (1999), 67(6), 2746-2762
CODEN: INFIBR; ISSN: 0019-9567
PUBLISHER: American Society for Microbiology
DOCUMENT TYPE: Journal
LANGUAGE: English

AB Three sep. studies, two involving active-**immunization** regimens and one involving a passive-transfer protocol, were conducted to initially screen and ultimately more fully assess several nontypeable Haemophilus influenzae outer membrane **proteins** or their derivs. for their relative protective efficacy in chinchilla models of otitis media. Initial screening of these antigens (P5-fimbrin, lipoprotein D, and P6), delivered singly or in combination with either Freund's adjuvant or alum, indicated that augmented bacterial clearance from the nasopharynx, the middle ears, or both anatomical sites could be induced by parenteral **immunization** with P5-fimbrin combined with lipoprotein D, lipoprotein D alone, or the synthetic **chimeric peptide** LB1 (derived from P5-fimbrin), resp. Data from a second study, wherein chinchillas were **immunized** with LB1 or lipoprotein D, each delivered with alum, again indicated that clearance of nontypeable H. influenzae could be augmented by **immunization** with either of these immunogens; however, when this adjuvant was used, both antibody titers in serum and efficacy were reduced. A third study was performed to investigate passive delivery of antisera directed against either LB1, lipoprotein D, nonacylated lipoprotein D, or a unique recombinant **peptide** designated LPD-LB1(f)2,1,3. The last three antiserum pools were generated by using the combined adjuvant of alum plus monophosphoryl lipid A. Passive transfer of sera specific for LB1 or LPD-LB1(f)2,1,3 to adenovirus-compromised chinchillas, prior to intranasal challenge with nontypeable H. influenzae, significantly reduced the severity of signs and incidence of otitis media which developed. Collectively, these data indicate the continued merit of further developing LB1 and LPD-LB1(f)2,1,3 as components of **vaccines** for otitis media.

REFERENCE COUNT: 75 THERE ARE 75 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L11 ANSWER 9 OF 11 CAPLUS COPYRIGHT 2004 ACS on STN DUPLICATE 4
ACCESSION NUMBER: 1998:785570 CAPLUS
DOCUMENT NUMBER: 130:37293
TITLE: Synthetic **chimeric** fimbrin **peptides**
INVENTOR(S): **Bakaletz, Lauren O.**; Kaumaya, Pravin T. P.
PATENT ASSIGNEE(S): The Ohio State University, USA
SOURCE: U.S., 16 pp.
CODEN: USXXAM
DOCUMENT TYPE: Patent
LANGUAGE: English
FAMILY ACC. NUM. COUNT: 1
PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
US 5843464	A	19981201	US 1995-460502	19950602
US 6436405	B1	20020820	US 1998-148711	19980904

US 2003113344 A1 20030619 US 2002-223711 20020819
PRIORITY APPLN. INFO.: US 1995-460502 A1 19950602
US 1998-148711 A3 19980904

AB The present invention provides synthetic **chimeric** fimbrin **peptides** which induce an immunogenic response in animals to non-typable Haemophilus influenzae and that do not require tedious purification techniques. The synthetic **chimeric** fimbrin **peptides** reduce the severity of otitis media caused by Haemophilus influenzae. The synthetic **chimeric** fimbrin **peptides** are synthesized using com. available **peptide** synthesizers. The synthetic **chimeric** fimbrin **peptides** comprises three **peptide** units. The first **peptide** unit is a subunit of the fimbrin **protein**. The second **peptide** unit is a T cell epitope. The third **peptide** unit is a linker **peptide** unit which joins the first and second **peptide** unit. The linking sequence preferably has from about 2 to about 15 amino acids, more preferably from about 2 to about 10 amino acids, most preferably from about 5 to about 6 amino acids. The synthetic **chimeric** fimbrin **peptides** are useful immunogens against NTHi and also useful as laboratory tool for detecting antibodies in sera. The invention also relates to an immunogenic composition containing the synthetic **chimeric** fimbrin **peptides** and a pharmacol. acceptable carrier.

REFERENCE COUNT: 14 THERE ARE 14 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L11 ANSWER 10 OF 11 CAPLUS COPYRIGHT 2004 ACS on STN DUPLICATE 5
ACCESSION NUMBER: 1997:560569 CAPLUS
DOCUMENT NUMBER: 127:233286
TITLE: Relative immunogenicity and efficacy of two synthetic **chimeric peptides** of fimbrin as **vaccinogens** against nasopharyngeal colonization by nontypeable Haemophilus influenzae in the chinchilla
AUTHOR(S): **Bakaletz, Lauren O.**; Leake, Edward R.; Billy, John M.; Kaumaya, Pravin T. P.
CORPORATE SOURCE: Otological Research Laboratories, Department of Otolaryngology, The Ohio State University, Columbus, OH, 43210-1282, USA
SOURCE: Vaccine (1997), 15(9), 955-961
CODEN: VACCDE; ISSN: 0264-410X
PUBLISHER: Elsevier
DOCUMENT TYPE: Journal
LANGUAGE: English

AB The OMP P5-homologous fimbriae of nontypeable H. influenzae (NTHi) are an adhesin and a virulence factor for otitis media in chinchilla models. The authors synthesized 2 **peptides** (LB1 and LB2) which incorporate determinants of the fimbrial subunit co-linearly synthesized with a "promiscuous" T-cell epitope from the fusion **protein** of measles virus. Sera obtained from **immunized** rabbits and chinchillas demonstrated significant reciprocal titers against both the homologous **peptide** and isolated fimbrial **protein**. Antisera also immunolabeled native fimbriae of whole unfixed NTHi. **Immunization**

with LB1 or fimbrin resulted in elimination of NTHi from the chinchilla nasopharynx 2-3 wk earlier than controls, resp.
REFERENCE COUNT: 45 THERE ARE 45 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L11 ANSWER 11 OF 11 CAPLUS COPYRIGHT 2004 ACS on STN
ACCESSION NUMBER: 1996:696093 CAPLUS
DOCUMENT NUMBER: 126:30044
TITLE: An investigation of the relative efficacy of two **chimeric** synthetic fimbrin **peptides** as immunogens against otitis media in a chinchilla model
AUTHOR(S): **Bakaletz, L. O.**; Kaumaya, P. T. P.; Leake, E.; Billy, J.; Murwin, D.
CORPORATE SOURCE: College Medicine, Ohio State University, Columbus, OH, 43210, USA
SOURCE: Peptides: Chemistry, Structure and Biology, Proceedings of the American Peptide Symposium, 14th, Columbus, Ohio, June 18-23, 1995 (1996), Meeting Date 1995, 778-779. Editor(s): Kaumaya, Pravin T. P.; Hodges, Robert S. Mayflower Scientific: Kingswinford, UK.
CODEN: 63NTAF
DOCUMENT TYPE: Conference
LANGUAGE: English
AB The authors synthesized two **peptides**, LB1 and LB2, from areas of fimbrin **protein** that were predicted to be potentially immunoreactive domains. Both **peptides** were able to induce high titer antibodies in chinchilla hosts. The **vaccine** potential of these **peptides** against otitis media will be tested in chinchillas.

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Devi, S
09/719379

24nov04 09:12:17 User219783 Session D2060.2

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File 65:Inside Conferences 1993-2004/Nov W3
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File 440:Current Contents Search(R) 1990-2004/Nov 24
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File 348:EUROPEAN PATENTS 1978-2004/Nov W02
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File 357:Derwent Biotech Res. _1982-2004/Nov W4
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File 113:European R&D Database 1997
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Set Items Description
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Set	Items	Description
S1	113	AU=(BAKALETZ, L? OR BAKALETZ L?)
S2	18	AU=(DEQUESNE, G? OR DEQUESNE G?)
S3	0	AU=(LOBERT Y? OR LOBERT, Y?)
S4	23863	L1 AND L2
S5	1467	(L1 OR L2) AND (VACCIN? OR IMMUNIS? OR IMMUNIZ?)
S6	5	S1 AND S2
S7	73	(S1 OR S2) AND (VACCIN? OR IMMUNIS? OR IMMUNIZ?)
S8	58	S7 AND (PROTEIN? ? OR PEPTIDE? ? OR POLYPROTEIN? ? OR POLY-PEPTIDE? ?)
S9	9	S8 AND CHIMER?
S10	13	S6 OR S9
S11	7	RD (unique items)

>>>No matching display code(s) found in file(s): 65, 113

11/3,AB/1 (Item 1 from file: 440)
DIALOG(R)File 440:Current Contents Search(R)
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15086258 Document Delivery Available: 000178939100021 References: 36
TITLE: Detection and characterization of pediatric serum antibody to the OMP P5-homologous adhesin of nontypeable Haemophilus influenzae during acute otitis media
AUTHOR(S): Novotny LA; Pichichero ME; Denoel PA; Neyt C; Vanderschrick S; **Dequesne G; Bakaletz LO (REPRINT)**
AUTHOR(S) E-MAIL: bakaletl@pediatrics.ohio-state.edu
CORPORATE SOURCE: Ohio State Univ, Div Mol Med,Dept Pediat, 700 Childrens Dr/Columbus//OH/43205 (REPRINT); Ohio State Univ, Div Mol Med,Dept Pediat, /Columbus//OH/43205; GlaxoSmithKline Biol, /Rixensart//Belgium/; Univ Rochester, Dept Microbiol & Immunol, /Rochester//NY/14642
PUBLICATION TYPE: JOURNAL
PUBLICATION: VACCINE, 2002, V20, N29-30 (OCT 4), P3590-3597
GENUINE ARTICLE#: 610AT
PUBLISHER: ELSEVIER SCI LTD, THE BOULEVARD, LANGFORD LANE, KIDLINGTON, OXFORD OX5 1GB, OXON, ENGLAND
ISSN: 0264-410X
LANGUAGE: English DOCUMENT TYPE: ARTICLE

ABSTRACT: We reported earlier that antibody in sera collected from seven

children with acute otitis media (AOM) due to nontypeable Haemophilus influenzae (NTHI) recognized immunodominant regions of P5-fimbrin just as we had observed in a chinchilla model of experimental NTHI-induced AOM. To expand upon those preliminary findings, we further characterized pediatric serum antibodies directed against this adhesin during AOM. Collectively, the data show that children respond immunologically to P5-fimbrin and they do so in a manner that allows for the distinction of sequence diversity within short linear peptides representing a focused region of this surface-exposed protein. The immune recognition we observed encourages us to further develop a P5-fimbrin based vaccine component.

11/3,AB/2 (Item 2 from file: 440)
DIALOG(R)File 440:Current Contents Search(R)

10591117 References: 75
TITLE: Protection against development of otitis media induced by nontypeable Haemophilus influenzae by both active and passive **immunization** in a chinchilla model of virus-bacterium superinfection
AUTHOR(S): **Bakaletz LO (REPRINT)**; Kennedy BJ; Novotny LA; Duquesne G; Cohen J; Lobet Y
AUTHOR(S) E-MAIL: BakaletL@pediatrics.ohio-state.edu
CORPORATE SOURCE: Ohio State Univ, Div Mol Med,Childrens Res Inst, Rm W302,700 Childrens Dr/Columbus//OH/43205 (REPRINT); Ohio State Univ, Dept Otolaryngol, /Columbus//OH/43210; SmithKline Beecham Biol, /Rixensart//Belgium/
PUBLICATION TYPE: JOURNAL
PUBLICATION: INFECTION AND IMMUNITY, 1999, V67, N6 (JUN), P2746-2762
GENUINE ARTICLE#: 199GX
PUBLISHER: AMER SOC MICROBIOLOGY, 1325 MASSACHUSETTS AVENUE, NW, WASHINGTON, DC 20005-4171 USA
ISSN: 0019-9567
LANGUAGE: English DOCUMENT TYPE: ARTICLE

ABSTRACT: Three separate studies, two involving active-**immunization** regimens and one involving a passive-transfer protocol, were conducted to initially screen and ultimately more fully assess several nontypeable Haemophilus influenzae outer membrane **proteins** or their derivatives for their relative protective efficacy in chinchilla models of otitis media. Initial screening of these antigens (PS-fimbrin, lipoprotein D, and P6), delivered singly or in combination with either Freund's adjuvant or alum, indicated that augmented bacterial clearance from the nasopharynx, the middle ears, or both anatomical sites could be induced by parenteral **immunization** with P5-fimbrin combined with lipoprotein D, lipoprotein D alone, or the synthetic **chimeric peptide** LB1 (derived from P5-fimbrin), respectively. Data from a second study, wherein chinchillas were **immunized** with LB1 or lipoprotein D, each delivered with alum, again indicated that clearance of nontypeable H. influenzae could be augmented by **immunization** with either of these immunogens; however, when this adjuvant was used, both antibody titers in serum and efficacy were reduced. A third study was performed to investigate passive delivery of antisera directed against either LB1, lipoprotein D, nonacylated lipoprotein D, or a unique recombinant **peptide** designated

LPD-LB1(f)(2,1,3). The last three antiserum pools were generated by using the combined adjuvant of alum plus monophosphoryl lipid A. Passive transfer of sera specific for LB1 or LPD-LB1(f)(2,1,3) to adenovirus-compromised chinchillas, prior to intranasal challenge with nontypeable H. influenzae, significantly reduced the severity of signs and incidence of otitis media which developed (P less than or equal to 0.001). Collectively, these data indicate the continued merit of further developing LB1 and LPD-LB1(f)(2,1,3) as components of **vaccines** for otitis media.

11/3,AB/3 (Item 3 from file: 440)
DIALOG(R)File 440:Current Contents Search(R)

08694240 References: 45
TITLE: Relative immunogenicity and efficacy of two synthetic **chimeric peptides** of fimbrin as **vaccinogens** against nasopharyngeal colonization by nontypeable Haemophilus influenzae in the chinchilla
AUTHOR(S): **Bakaletz LO (REPRINT)**; Leake ER; Billy JM; Kaumaya PTP
CORPORATE SOURCE: OHIO STATE UNIV,DEPT OTOLARYNGOL, OTOL RES LAB, ROOM 4331 UHC, 456 W 10TH AVE/COLUMBUS//OH/43210 (REPRINT); OHIO STATE UNIV,COLL MED, DEPT OBSTET & GYNECOL/COLUMBUS//OH/43210
PUBLICATION TYPE: JOURNAL
PUBLICATION: VACCINE, 1997, V15, N9 (JUN), P955-961
GENUINE ARTICLE#: XN853
PUBLISHER: ELSEVIER SCI LTD, THE BOULEVARD, LANGFORD LANE, KIDLINGTON, OXFORD, OXON, ENGLAND OX5 1GB
ISSN: 0264-410X
LANGUAGE: English DOCUMENT TYPE: ARTICLE

ABSTRACT: The OMP P5-homologous fimbriae of nontypeable Haemophilus influenzae (NTHi) are an adhesin and a virulence factor for otitis media in chinchilla models. We synthesized two **peptides** (LB1 and LB2) which incorporate determinants of the fimbrial subunit co-linearly synthesized with a ''promiscuous'' T-cell epitope from the fusion **protein** of measles virus. Sera obtained from **immunized** rabbits and chinchillas demonstrated significant reciprocal titers against both the homologous **peptide** and isolated fimbrial **protein**. Antisera also immunolabeled native fimbriae of whole unfixed NTHi. **Immunization** with LB1 or fimbrin resulted in elimination of NTHi from the chinchilla nasopharynx 2-3 weeks earlier than controls, respectively. (C) 1997 Elsevier Science Ltd.

11/3,AB/4 (Item 1 from file: 348)
DIALOG(R)File 348:EUROPEAN PATENTS

01118363
VACCINE
IMPFSTOFF
VACCIN
PATENT ASSIGNEE:
SMITHKLINE BEECHAM BIOLOGICALS (S.A.), formerly SMITHKLINE BIOLOGICALS (S.A.), (1293470), Rue de l'Institut 89, 1330 Rixensart, (BE), (Applicant designated States: all)

THE OHIO STATE UNIVERSITY RESEARCH FOUNDATION, (402133), 1960 Kenny Road, Columbus, Ohio 43210-1063, (US), (Applicant designated States: all)
INVENTOR:
BAKALETZ, Lauren, O., 700 Children's Drive, Colombus, OH 43205, (US)
COHEN, Joseph, Rue de l'Institut 89, B-1330 Rixensart, (BE)
DEQUESNE, Guy, Rue de l'Institut 89, B-1330 Rixensart, (BE)
LOBET, Yves, Rue de l'Institut 89, B-1330 Rixensart, (BE
LEGAL REPRESENTATIVE:
Privett, Kathryn Louise et al (81082), SmithKline Beecham plc, Corporate Intellectual Property, Two New Horizons Court - 2/NHC/1, Great West Road, Brentford, Middlesex TW8 9EP, (GB)
PATENT (CC, No, Kind, Date): EP 1083926 A1 010321 (Basic)
WO 9964067 991216
APPLICATION (CC, No, Date): EP 99924543 990528; WO 99US11980 990528
PRIORITY (CC, No, Date): GB 9812613 980611
DESIGNATED STATES: AT; BE; CH; CY; DE; DK; ES; FI; FR; GB; GR; IE; IT; LI; LU; MC; NL; PT; SE
EXTENDED DESIGNATED STATES: SI
INTERNATIONAL PATENT CLASS: A61K-039/02; A61K-039/00; A61K-039/102; A61K-038/00; C07H-021/04; C07H-021/02; C07K-016/00; C12P-021/06; C12P-021/04; C12N-001/20; G01N-033/53
NOTE:
No A-document published by EPO
LANGUAGE (Publication,Procedural,Application): English; English; English

11/3,AB/5 (Item 1 from file: 357)
DIALOG(R)File 357:Derwent Biotech Res.

0328338 DBR Accession No.: 2004-00630 PATENT
Novel synthetic **chimeric** fimbrin **peptide** LB1 or LB2 comprising a first **peptide** unit, T cell epitope as second **peptide** unit and third linker **peptide** unit, useful for preventing or reducing severity of otitis media - **chimeric protein immunization** in chinchilla for **vaccine**
AUTHOR: **BAKALETZ L O**; KAUMAYA P T P
PATENT ASSIGNEE: BAKALETZ L O; KAUMAYA P T P 2003
PATENT NUMBER: US 20030113344 PATENT DATE: 20030619 WPI ACCESSION NO.: 2003-810881 (200376)
PRIORITY APPLIC. NO.: US 223711 APPLIC. DATE: 20020819
NATIONAL APPLIC. NO.: US 223711 APPLIC. DATE: 20020819
LANGUAGE: English
ABSTRACT: DERWENT ABSTRACT: NOVELTY - A synthetic **chimeric** fimbrin **peptide** LB1 or LB2 (I) comprises a first **peptide** unit (II) having a fully defined sequence of 18 amino acids as given in the specification, a second **peptide** unit (III) containing a T cell epitope and a third linker **peptide** (IV) which connects the (II) to (III), is new. DETAILED DESCRIPTION - A synthetic **chimeric** fimbrin **peptide** LB1 or LB2 (I) comprising a first **peptide** unit (II) having a amino acid sequence (A1) or (A2), a second **peptide** unit (III) containing a T cell epitope and a third linker **peptide** (IV) which connects the (II) to (III).An INDEPENDENT CLAIM is also included for a synthetic **peptide** having the amino acid sequence (A1) or (A2). Arg-Ser-Asp-Tyr-Lys-Phe-Tyr-Glu-Asp-Leu-Asn-Gly-

Thr-Arg-Asn-His-Lys-Lys (A1) Tyr-Gln-Trp-Leu-Thr-Arg-Val-Gly-Lys-Tyr-Ar g-Pro-Gln- Asp-Lys-Pro-Asn-Thr (A2) BIOTECHNOLOGY - Preferred **Chimeric Peptide** : (III) is chosen from (A3)-(A7) and preferably (A8): Asn-Ser-Val-Asp-Asp-Ala-Leu-Ile-Asn-Ser-Thr-Ile-Tyr-Se r-Tyr- Phe-Pro-Ser-Val (A3) Pro-Gly-Ile-Asn-Gly-Lys-Ala-Ile-His-Leu-Val -Asn-Asn-Gln-Ser-Ser-Glu (A4) Gln-Tyr-Ile-Lys-Ala-Asn-Ser-Lys-Phe-Ile-G ly-Ile-Thr-Glu-Leu (A5) Phe-Asn-Asn-Phe-Thr-Val-Ser-Phe-Trp-Leu-Arg-Val -Pro-Lys-Val-Ser-Ala-Ser-His-Leu-Glu (A6) Phe-Phe-Leu-Leu-Thr-Arg-Ile-L eu-Thr-Ile-Pro-Gln-Ser-Leu-Asn (A7) Leu-Ser-Leu- Ile-Lys-Gly-Val-Ile-Va l-His-Arg-Leu-Glu-Gly-Val-Glu (A8) (IV) has 1-15 amino acids. (I) has a amino acids sequence (A9) - (A11): Arg-Ser-Asp-Tyr-Lys-Phe-Tyr-Glu-Asp-Ala-Asn-Gly-Thr-Arg-Asp-His-Lys-Lys-Gly-Pro-Ser-Leu-Lys-Leu-Leu-Ser-Leu -Ile-Lys-Gly-Val-Ile-Val-His-Arg-Leu-Glu-Gly-Val-Glu (A10) Tyr-Gln-Trp-Leu-Thr-Arg-Val- Gly-Lys-Tyr-Arg-Pro-Gln-Asp-Lys-Pro-Asn-Thr-Gly-Pro-Se r-Leu-Lys- Leu-Leu-Ser-Leu-Ile-Lys-Gly-Val-Ile-Val-His-Arg-Leu-Glu-Gly-Val-Gly (A11) ACTIVITY - Auditory; Antiinflammatory. Nasopharyngeal colonization by non typable Haemophilus influenzae (NTHi) was examined. Five cohorts of four chinchillas each were actively **immunized** with one of the following preparations in complete Freund's adjuvant or saline control preparation; 100 micrograms of the synthetic **chimeric** fimbrin **peptide** LB1, 100 micrograms of a total outer membrane **protein** preparation from strain 1128, 100 micrograms of the synthetic **chimeric** fimbrin **peptide** LB2, 10 micrograms isolated fimbrin **protein** preparation from strain 1128. The total outer membrane preparation and fimbrin were assessed for endotoxin content prior to their use as an immunogen by a chromogenic Amoebocyte Lysate assay. The preparations were subcutaneously injected into the chinchillas. Then 30 days later the animals received a booster of one-half of the initial dosage of the same immunogen but in incomplete Freund's adjuvant. Ten days later they received 6 x 106 TCID50 adenovirus intranasally. Thereafter, these five cohorts were divided into two groups each and challenged intranasally, about 5 x 107 colony forming units (cfu) of NTHi strain 1128. The chinchillas were subject to nasopharyngeal lavage over a 21 day period, and the lavage fluid was examined and quantified for NTHi. The NTHi concentration was determined by plating on selective media. The NTHi lavage fluid concentration was plotted over time. **Immunization** with LB1 and LB2 lowered the NTHi in lavage fluid to 0 by day 21 in contrast to the control fluid which had 104 NTH1 present on day 21. The LB2 performed less well at the higher challenge dose of bacteria. Nasopharyngeal colonization is an initial step required for the development of the disease, otitis media. Since the **immunization** with synthetic **chimeric** fimbrin **peptide** inhibits nasopharyngeal colonization of NTHi, the synthetic **chimeric** fimbrin **peptides** inhibit the development of otitis media. MECHANISM OF ACTION - **Vaccine**. USE - (I) is useful for inducing an immune response in animals against non-typable Haemophilus influenzae (NTHi), which involves administering an immunogenic composition (V) comprising (I) and a carrier (claimed). (I) is useful for preventing or reducing adherence of NTHi to host cells thereby preventing or reducing the severity of otitis media. (I) is useful in laboratory assays, e.g., to detect antibodies in sera to NTHi. (15 pages)

11/3,AB/6 (Item 2 from file: 357)

DIALOG(R)File 357:Derwent Biotech Res.

0321938 DBR Accession Number: 2003-23078 PATENT
Synthetic **chimeric** fimbrin **peptide**, useful for treating Haemophilus influenzae infections - for use in Haemophilus influenzae infection and otitis media therapy
AUTHOR: **BAKALETZ L O**; KAUMAYA P T P
PATENT ASSIGNEE: UNIV OHIO STATE 2002
PATENT NUMBER: US 6436405 PATENT DATE: 20020820 WPI ACCESSION NO.: 2003-615247 (200358)
PRIORITY APPLIC. NO.: US 148711 APPLIC. DATE: 19980904
NATIONAL APPLIC. NO.: US 148711 APPLIC. DATE: 19980904
LANGUAGE: English
ABSTRACT: DERWENT ABSTRACT: NOVELTY - A synthetic **chimeric** fimbrin **peptide** (I), comprising 12-18 residues of an 18 amino acid sequence (S1), given in the specification, is new. DETAILED DESCRIPTION - INDEPENDENT CLAIMS are also included for: (1) a synthetic **chimeric peptide** comprising (I), a **peptide** linker and a T cell epitope; (2) a synthetic **chimeric peptide** comprising 12-18 residues of an 18 amino acid sequence (S2), given in the specification, a **peptide** linker and a T cell epitope; and (3) an immunogenic composition which induces an immune response against non-typable Haemophilus influenzae, comprising the **peptide** of (1) and a carrier. ACTIVITY - Antibacterial; Auditory. Two rabbits were **immunized** with 500 micro-g LB1 synthetic **chimeric** fimbrin **peptide** in complete Freund's adjuvant (CFA), and a second dose of 400 micro-g 21 days later. A third dose of 400 micro-g in CFA was administered 42 days later. Sera was obtained three weeks after the final dose, and enzyme linked immunosorbent assay was used to determine the titer of the rabbit sera. The titer was 20000 for LB1 in CFA, and 100000 for LB1 in phosphate buffered saline. MECHANISM OF ACTION - None given. USE - For treating a Haemophilus influenzae infection (claimed) and otitis media. ADVANTAGE - The synthetic **peptides** do not require tedious purification techniques.(16 pages)

11/3,AB/7 (Item 3 from file: 357)
DIALOG(R)File 357:Derwent Biotech Res.

0249686 DBR Accession Number: 2000-04176 PATENT
Novel antigenic P5-like fimbrin subunit **peptides** used in **vaccines** against Haemophilus influenza - recombinant **protein** production and purification via vector-mediated gene transfer and expression in host cell for otitis media diagnosis, therapy and in recombinant **vaccine**
AUTHOR: **Bakaletz L O**; Cohen J; **Dequesne G**; Lobet Y
CORPORATE SOURCE: Rixensart, Belgium; Colombus, OH, USA.
PATENT ASSIGNEE: SK-Beecham; Univ.Ohio-State 1999
PATENT NUMBER: WO 9964067 PATENT DATE: 19991216 WPI ACCESSION NO.: 2000-116457 (2010)
PRIORITY APPLIC. NO.: GB 9812613 APPLIC. DATE: 19980611
NATIONAL APPLIC. NO.: WO 99US11980 APPLIC. DATE: 19990528
LANGUAGE: English
ABSTRACT: Antigenic P5-like fimbrin subunit **peptides** (I) of P5-like

fimbrin **proteins** from various Haemophilus influenza (HI) strains, are new. Also claimed are: a **chimeric protein** containing (I) covalently linked to a carrier **protein** which consists of at least one T-lymphocyte epitope; a **chimeric protein** containing 3 (I) subunits and **lipoprotein**-D; a **vaccine** composition and its use to prevent or treat HI disease; DNA or RNA molecules (II) which encode (I); an expression vector containing (II); a host cell transformed with the vector; the recombinant production of (I) by culturing the transformed host cells; an antibody specific for (I); and a kit for diagnosing HI infections. The above may be useful for diagnosing, preventing and treating HI infections, such as otitis media, sinusitis, conjunctivitis or lower respiratory tract infection. The **proteins** may also be used in recombinant **vaccines** and the antibodies and DNA probes may be useful for the diagnosis. (I) was purified from the host cells using an immobilized nickel column, a cation-exchange column and a size-exclusion chromatography step. (68pp)

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